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Micky Tripathi, Ph.D., M.P.P.
Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St, SW
Washington, DC 20201

RE: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing [RIN 0955-AA03]

Dear Dr. Tripathi,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease, Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN is committed to efforts that will promote electronic health record (EHR) interoperability and ensure that the 21st Century Cures Act requirements are implemented in a manner that promotes transparency and information sharing across the United States healthcare system. Challenges associated with interoperability are some of the most critical challenges forcing clinicians to spend too much time on low-value clerical work and less time on direct patient care. The AAN appreciates the Office of the National Coordinator's (ONC) commitment to ensuring that key provisions impacting health information technology (IT) and the sharing of electronic health information (EHI) are updated in a timely manner. The AAN believes it is critical that as updates are made to the existing regulatory framework that ONC account for the perspectives and needs of both neurology providers and neurology patients.

New and Revised Standards and Certification Criteria

Electronic Case Reporting

ONC is proposing to require that Health IT Modules support electronic case reporting using consensus-based, industry-developed HL7 and FHIR

standards. The AAN supports this proposal as there has been increasing adoption and use among neurologists of electronic case reporting functionality, in particular supporting surveillance of neurologic disorders. The AAN concurs with ONC that this proposal will promote improved bi-directional exchange of health data between providers and public health authorities. In implementing this proposal, it will be critical to ensure that the collection and submission of the relevant data must not be onerous for practices.

Decision Support Interventions and Predictive Models

ONC is proposing to update the existing Clinical Decision Support criterion within the Health IT Certification program to reflect a wide variety of contemporary and emerging software functionalities that aid user decision-making in health care, including artificial intelligence (AI) and machine learning (ML).

In support of this effort, ONC is proposing to define the term "predictive decision support intervention" as "technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis."[1] Health IT modules that enable or interface with algorithms or models who meet the above definition will be required to make technical, performance, governance, and oversight information available to the end user. Specifically, impacted modules will be required to enable "a user to review a plain language description of source attribute information as indicated at a minimum via direct display, drill down, or link out from a Health IT Module."[2]

The AAN supports ONC's goal of improving transparency and enhancing trustworthiness of decision support intervention (DSI) tools as they are increasingly utilized across the healthcare system. The AAN concurs with ONC that it is critical for the end user to understand how a predictive DSI is designed, developed, trained, evaluated, and should be used by the end-user. The AAN also supports ONC's commitment to advancing health equity by design by addressing bias and health disparities that are potentially aggravated by expanded use of DSIs that are created based on flawed inputs and which fail to disclose critical source information. The AAN is committed to working with ONC to ensure that the needs of traditionally at-risk patient populations and those already subject to health care disparities are appropriately accounted for when developing policy impacting the development and promulgation of DSIs.

Although the AAN is highly supportive of the intent of this proposal, the potential scope and highly technical nature of the requirements pose significant challenges for stakeholders. The AAN believes that the focus of this proposed update to the criterion may be overly broad and should instead be narrowed to specifically focus on AI and ML algorithms as there are substantial risks of bias associated with these models if they are not constructed in a manner that allows the end user to understand how they were constructed and will be maintained going forward. The AAN believes that such disclosure is a best practice for AI and ML models and concurs with ONC that it is critical that the end user have the necessary

[1] 88 Fed. Reg. at 23785
[2] 88 Fed. Reg. at 23909

information to determine whether a particular tool is fair, appropriate, valid, effective, and safe. Furthermore, the AAN is concerned that the proposed definition may implicate algorithms that are not directly tied to clinical workflows. A particular DSI tool could be built on ML, but it may not be warranted to subject that DSI to the disclosure requirements if its output does not impact clinical decision making and simply serves to enhance a non-clinical workflow. In support of refining this proposed rule, the AAN offers the following illustrative examples of algorithms that may reasonably fall under the proposed definition but for which it may not be appropriate to require the degree of source attribute disclosure proposed in this rule:

- Workflow enhancement tools such as a checklist to close an encounter, discharge a patient, or to adhere to proper coding.
- Legacy CDS that provides for some exceptions for simple advisory, non-hard stop pathways if they have been in use for a significant period of time and can be reasonably applicable across the practice without being discriminatory.
- Care pathways to drive certain patients to new hires who may have more timely availability for patients.
- A simple alert showing the provider that a patient has a similar name to another patient on the provider's list.
- A simple age-based alert to ensure that a provider places an order for a pediatric patient with the pediatric clinic, rather than the adult clinic.
- Order sets and preference lists that guide users based on the consensus of the local practice or business administrator.

To aid in our understanding of this proposal, if finalized, the AAN requests that ONC publish a list of illustrative examples of algorithms and models that would fall under the final definition of this term.

The AAN appreciates ONC's clarification that the agency differentiates predictive decision support interventions (DSIs) "as those that support decision-making by learning or deriving relationships to produce an output, rather than those that rely on pre-defined rules based on expert consensus, such as computable clinical guidelines, to support decision-making."[3] The AAN believes it is critical that ONC account for the needs of clinical guideline developers in this proposed rule so that undue burdens are not placed on the guideline development process as DSI tools are developed and implemented in part based on clinical guidelines.

Although the AAN is supportive of the proposed disclosures, the AAN believes that these requirements may stifle innovation and slow integration of DSI into the EHR. The AAN believes that it is likely that the disclosure requirements are likely to increase the cost and resources associated with maintaining certified EHR technology. The AAN is also concerned that these requirements may impact vendor implementation of other critical updates and projects and urges ONC to reconsider whether the implementation timeline will be feasible for vendors, without passing substantial cost along to the provider, health systems, or specialty societies.

[3] 88 Fed. Reg. at 23785

The AAN requests clarification regarding the requirement that the validity and fairness of a predicted output be evaluated in local data if available. The AAN is concerned that it may not be feasible for practices and health systems to do this and that it may not be practical for end users to repeatedly test and validate a model on local data to ensure that a particular DSI does not exacerbate disparities or reinforce bias.

The AAN urges ONC to closely monitor implementation of the requirements impacting DSI to ensure programmatic success and so that stakeholders receive the information that is needed to improve transparency and enhance the trustworthiness of DSI. The AAN also requests that ONC closely monitor the impact of these proposals on practices and health systems to determine whether the burdens and associated costs of implementation are being passed along to the provider. The AAN urges ONC to consider slowing the implementation timeframe if it is determined that implementation is creating undue burdens for practices or patients.

Patient Requested Restrictions Certification Criterion

ONC is proposing a requirement so that health IT developers must enable functionality so that, based on a patient request, a user may flag whether certain data elements need to be restricted from being subsequently used or disclosed. Based on this request, developers would be required to prevent any data flagged from being included in a use or disclosure, based on the patient's direction. The AAN is supportive of this concept and believes it is important for patients to be empowered to mark their own information as sensitive, while ensuring that providers are not engaging in information blocking. Although we are supportive conceptually, the AAN cautions that implementation may be difficult for smaller practices, without robust EHR functionality. It is critical that the EHR vendor provide necessary support to small practices to implement this additional functionality so that the burdens of implementing do not disproportionately pose challenges for small practices. Additionally, the AAN urges caution regarding how implementation of this functionality may interfere with coordination of care.

The AAN believes that this proposal is likely to be especially beneficial in relation to genomic information. The AAN believes that patients should have the ability to specifically request that genomic information not be shared, until the patient has been able to discuss the information with a genetic counselor or a relevant provider, like a neurologist, to make a decision regarding the appropriate sharing of that information. This capability will be particularly important for patients receiving information related to a neurodegenerative disorder, like Huntington's Disease.

Requirement for Health IT Developers to Update their Previously Certified Health IT

ONC is proposing to require that health IT developers participating in the Health IT Certification Program "must update their certified Health IT Modules and provide that updated certified health IT to customers in accordance with the timelines defined for a specific criterion or standard."[4] The AAN supports this requirement and believes it is critical that vendors are held accountable to ensure that their products are consistent with current

[4] 87 Fed. Reg. at 23753

certification requirements. Although we are supportive of this provision, the AAN believes it is critical that associated costs with complying with these timelines should not be passed along to the provider and that the unique needs of individual practices and providers must be accounted for when implementing updates to certified EHRs.

Insights Condition and Maintenance of Certification Requirements

ONC is proposing to implement requirements from the 21st Century Cures Act to establish the EHR Reporting Program to provide transparent reporting of measures of the performance of certified health IT. In support of this effort, ONC is proposing to establish the Insights Condition of Certification with the aim of addressing information gaps in the marketplace, providing insight relating to the use of specific functionality, and making information available regarding consumers' experiences with certified health IT. The AAN supports the development of these metrics and believes that doing so is critical to promote interoperability and transparency in the marketplace. The AAN believes this effort is critical for neurology in particular, as neurologists need interoperable data transfer to share information on patients with primary neurologic conditions with other specialists and to receive referral-related information from primary care providers.

Although the AAN supports this effort, we caution that although vendors are required to report on these metrics, the end-user will likely be required by their vendor to ensure that their practice maps to these metrics and validates them as accurate. Doing so is likely to be a time and resource intensive effort for practices. While the AAN appreciates that ONC is proposing to implement these requirements over a two-year time frame, to lessen associated burden, the AAN recommends a longer phased in approach to ensure that practices are not overly strained by implementation of this program and to ensure that metrics can be validated before phasing in future ones.

Request for Information on Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities

This request for information notes that ONC intends to propose in future rulemaking the establishment of a real-time prescription benefit health IT certification criterion. This criterion would certify health IT to enable a provider to view within the electronic prescribing workflow, at the point of care, patient specific benefit information, including estimated cost and viable alternatives. ONC is also considering enabling the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and to identify coverage restrictions and alternatives when they exist. Further, ONC is examining whether to support functionality related to drug interaction checks, medication history, formulary benefit management, eligibility checks, electronic prior authorization, and electronic prescribing.

The AAN believes it would be beneficial for providers to have the information under consideration at the point of prescribing, as long as it can be provided quickly and without interrupting the workflow. Specifically, the AAN believes that inclusion of information relating to prior authorization has the potential to reduce administrative burden on providers and their staff, while providing much needed transparency. It will be critical for this

functionality to be implemented so that data can be seamlessly transferred with the pharmacy and the insurer, so that the relevant information can be accessed without requiring input from the end user.

While the AAN believes it is important to promote seamless integration of care-related information into the EHR, the AAN cautions ONC regarding integration of drug interaction checks. Often there are competing products that are importing drug interaction checks that are run based on medication lists that are a combination of existing prescription information and "patient-reported" and medical assistant entered information that are not always accurate. The AAN believes it is critical that if this functionality is included in a future iteration of the Health IT Certification program, that there must be flexibility to allow for the correction of clinically inappropriate and inaccurate information in submissions to facilitate review. The AAN also notes that there are routinely instances in neurologic care in which drugs are prescribed multiple times, with varying schedules, which may trigger interaction flags. An illustrative example of this is a Parkinson's disease patient on three formulations of levodopa, all of which may be flagged as duplicate or unnecessary, when they are all used appropriately. There is also the potential for unnecessary flags in cases in which a medication is prescribed off-label, which is common practice for a number of neurologic drugs. When establishing this criterion, it will be critical that the user has the ability to suppress excess need for interaction checks.

Real Time Prescription Benefit Certification Scope

ONC is also requesting comments on whether a real-time prescription benefit criterion should also require demonstration of support for products that are not defined as medications but may also be included in a RTPB transaction, namely vaccines and medical devices or supplies, specifically ONC is asking the following:

- What benefits would come from supporting the exchange of prescription benefit information for vaccines, medical devices, or supplies?

The AAN believes that the primary benefit from supporting the exchange of this information would be to help practices and providers understand relevant benefit information at the point of prescribing to the degree to which knowing that information may impact a prescribing decision. Clear and accurate information will be critical to ensuring that exchange of this information aids in provider decision-making rather than creating additional burdens.

- What challenges would be involved in supporting the exchange of prescription benefit information for vaccines, medical devices, or supplies?

The AAN notes that currently EHRs do not always represent medical device and supply information accurately or discreetly. Frequently, a generic order is required which may be fulfilled by two or more suppliers who may not have the same device available. Discrete and accurate device- and supply-specific information will be needed for this information to be useful to providers and patients.

Electronic Prior Authorization

ONC notes that after receiving a Real-Time Prescription Benefit Request transaction, a processor, PBM, or adjudicator will determine eligibility for the identified patient and determine if the product requires prior authorization. In the response, a health care provider may receive notification that a prior authorization is needed for the prescription. ONC requests comment on the potential incorporation of these transactions into the "Electronic prescribing" certification criterion and whether the agency should consider requiring certification to these transactions in a future rulemaking.

The AAN supports efforts that allow physicians to check PA requirements and drug formulary status at the point of prescribing in EHRs and support informed conversations with patients about therapy costs. Health care providers face persistent challenges associated with obtaining formulary and benefit information. Often insurance companies will not provide real time information and instead require a provider to send a prescription first. This results in what is often a time-consuming and labor-intensive process to receive an authorization. This leads to unnecessary strain on the practice, frustration for the patient, and may result in a delay in treatment. Universal standards-based solutions and integration into the EHR are necessary to address these challenges.

While the AAN is highly supportive of the required integration of electronic prior authorization processing capabilities at the point of prescribing, we note that AAN members have expressed frustration with existing electronic prior authorization systems relating to inaccurate or inadequate population of information from the EHR to the relevant form and payer. The AAN believes if data can be accurately and comprehensively pulled electronically rather than requiring manual entry, it will likely alleviate burden on providers and staff. Alternatively, inadequate systems and standards may lead to an increase in administrative burdens as additional data entry responsibilities would be placed on the provider and support staff. Furthermore, the AAN is concerned with the burdens associated with incrementing workflows and potentially including redundant steps that would keep providers from being able to spend more time with their patients, and less time on paperwork.

Information Blocking Enhancements

Third Party Seeking Modification Use

ONC is proposing to clarify the infeasibility exception as it relates to information blocking. Information blocking is currently defined "as business, technical, and organizational practices that prevent or materially discourage the access, exchange or use of electronic health information (EHI) when an Actor knows, or (for some Actors like EHR vendors) should know, that these practices are likely to interfere with access, exchange, or use of EHI."[5] The term "use" is defined to include both read and write access and is bidirectional. Given concerns related to the potential adverse consequences associated with third party modification of EHI, ONC is clarifying the existing infeasibility exception so that requests to modify EHI (including but not limited to creation and deletion functionality) could be

[5] What Is Information Blocking?, Jan. 2021, www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf.

considered infeasible, unless the request is from a health care provider requesting such use from an actor that is its business associate. The AAN agrees with ONC that the presumption of infeasibility will reduce the burden of determining whether a particular request meets the existing infeasibility information blocking exception and will provide actors with much needed certainty.

Manner Exception Exhausted

The AAN supports ONC's efforts to clarify the infeasibility exception in cases in which the actor either could not reach an agreement with the requestor on the manner in which the request would be fulfilled or in cases in which it is technically infeasible for an actor to fulfill a request for EHI in the manner requested. The AAN supports the proposal and believes it provides much needed certainty, while reducing inappropriate diversion of resources to fulfill requests in atypical and non-interoperable, standards-based manners. The AAN believes that this proposal should be implemented to minimize the burdens associated with compliance for the actor.

Manner Exception – TEFCA Reasonable and Necessary Activities

ONC is proposing to add a TEFCA condition to the information blocking manner exception. The TEFCA condition would offer Qualified Health Information Networks (QHINs), participants, and subparticipants in TEFCA the ability to fulfill EHI requests from any QHIN, participant, or subparticipant in TEFCA using TEFCA means, even if the requestor would have preferred to use another means. The AAN is supportive of the goals of TEFCA and supports the implementation of policy that promotes this national framework for interoperable exchange of health information.

Conclusion

The AAN appreciates the opportunity to comment on the various provisions of this proposed rule. The AAN is committed to working with ONC to reduce the administrative burdens on providers and to promote the seamless sharing of EHI across the healthcare system. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

Carlayne E. Jackson, MD, FAAN
President, American Academy of Neurology